

# Office Action Summary

## Application No.

10/533,826

## Applicant(s)

MARX ET AL.

## Examiner

MAURY AUDET

## Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 08 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1, 7-14, 20-25, 31-41, 43 and 48-51 is/are pending in the application.
- 4a) Of the above claim(s) 11-14, 20-25, 31-33, 37-41, 43, 50 and 51 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 7-10, 34-36, 48 and 49 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 January 2009 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-940)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☒ Interview Summary (PTO-413)  
Paper No(s)/Mail Date Herewith
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

The present application has been transferred from former Examiner Young to the present Examiner.

Applicant's amendment and response is acknowledged.

The Examiner telephoned Applicant's representative to indicate the only outstanding issue is the filing of a Terminal Disclaimer over at least the '620 patent. And to inquire if Applicant was interested in filing a Terminal Disclaimer over the '620 or any other patent claims that have issued from this family over products consisting of SEQ ID NO: 1. Applicant's representative thanked the Examiner but asked the present Office Action be sent in writing for consideration.

### ***Election/Restrictions***

As previously noted, Applicant's **election without traverse of Group I, original claims 1-10 and 34-36, as drawn to the elected peptide of the invention, a peptide consisting of SEQ ID NO: 1** in the reply filed on 7/10/07 is acknowledged.

Amended claims 11-14, 20-25, 31-41, 43, and new claims 50-51 are now withdrawn from consideration. **Claims 1, 7-10, 34-36 and new claims 48-49 have only been examined in so far as they read upon the elected peptide of the invention, a peptide consisting of SEQ ID NO: 1.**

In response hereto, Applicant is asked to put the claims with their proper status identifier.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The rejection of claims 1, 7-10, 34-36, and 48-49 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 7,122,620 (09/847,790), is maintained for the reasons of record. Applicant's arguments have been considered but are not found persuasive. Namely, the use of liposomes for increased cellular uptake of other compounds is a known result of the use of liposomes. Thus, the use of a peptide “consisting of SEQ ID NO: 1” remains drawn to a product, namely another composition, of which nothing would have prevented the ‘620 product claims to the same peptide from being use therein, especially given the ‘620’s composition open “comprising” transition phrase to any other known products/molecules being capable of use within the ‘620’s composition.

As noted previously, although the conflicting claims are not identical, they are not patentably distinct from each other because the '620 patent is drawn to a peptide or any type of composition comprising identical SEQ ID NO: 1. Although the present application is to a "liposomal" compositions comprising SEQ ID NO: 1, compositions comprising liposomes need no reference for an introduction. The use of liposomes to carry e.g. other active agents, in combination with peptides has been well known in the art for over a decade a routinely used form of compositions.

Regarding the previous recitation that absent evidence to the contrary that these specific liposomes carry some other unexpected property not routinely used within the peptide composition arts – which was not shown. Namely, the asserted unexpected property is liposomes known property – that they increase the cellular uptake of other compounds.

The rejection of claims 1, 7-10, 34-36, and 48-49 as provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 11-20 of copending Application No. US 20070009571 (11/490,033), is maintained for the reasons of record. As noted previously, although the conflicting claims are not identical, they are not patentably distinct from each other because the '571 claims 11-20 are drawn to compositions/products comprising SEQ ID NO: 1, identical to presently elected SEQ ID NO: 1, and elected products thereof. Although the present application is to a "liposomal" compositions comprising SEQ ID NO: 1, compositions comprising liposomes need no reference for an introduction. The use of liposomes to carry e.g. other active agents, in combination with peptides has been well known in the art for over a decade a routinely used form of compositions.

Absent evidence to the contrary the these specific liposomes carry some other unexpected property not routinely used within the peptide composition arts.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The rejection of claims 1, 7-10, 34-36, and 48-49 as provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2 of copending Application No.11/601,024 (US 20070066535), is maintained for the reasons of record. As noted previously, although the conflicting claims are not identical, they are not patentably distinct from each other because the '024 claims 1-2 are drawn to a peptide/product comprising a peptide of at least 50-70% identity to the carboxy termini of fibrinogen. Read in light of the specification, SEQ ID NO: 14 meets the limitations of 1-2 of '024 and SEQ ID NO: 14 is identical to presently elected SEQ ID NO: 1, and elected products thereof. Although the present application is to a "liposomal" compositions comprising SEQ ID NO: 1, compositions comprising liposomes need no reference for an introduction. The use of liposomes to carry e.g. other active agents, in combination with peptides has been well known in the art for over a decade a routinely used form of compositions. Absent evidence to the contrary the these specific liposomes carry some other unexpected property not routinely used within the peptide composition arts.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Citation of Pertinent Art Not Relied Upon***

As previously noted, the prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Regarding the subject matter of haptotactic peptides, Applicant has one other issued patent, related, though drawn to distinct haptotactic peptides (all under examination by Examiners other than the present):

US 7,148,190 (10/181,187)

***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAURY AUDET whose telephone number is (571)272-0960. The examiner can normally be reached on M-Th. 7AM-5:30PM (10 Hrs.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MA, 4/27/2009

/Maury Audet/  
Examiner, Art Unit 1654